K100418

SEP 3 2010

## 510(K) SUMMARY

**1. 510(k) Owner:**

Covidien
15 Hampshire Street
Mansfield, MA 02048
Telephone: (508) 261 – 6596
Fax: (508) 261 – 8461

Contact: Mr. Wing Ng
Title: Senior Regulatory Specialist
Date Prepared: February 12, 2010

**2. Device:**

Trade Name: Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode
Common Name: Electrode
Classification Name: Cutaneous Electrode
Regulation Number: 21 CFR 882.1320
Product Code: GXY
Classification: Class II

**3. Predicate Devices:**

- Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode (K083350)
- TENS Reusable Electrode (K902195)

**4. Device Description:**

The Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode is a transcutaneous electrical nerve stimulation (TENS), neuromuscular electrical stimulation (NMES), functional electrical stimulation (FES) electrode. It is composed of a cover, reinforcement film, lead wire, glue, silver print, conductive member, conductive hydrogel, pressure sensitive adhesive, and a release liner. During electrotherapy, current from the electrical stimulation device is delivered through the lead wire, silver printed conductive member, conductive hydrogel, and to the patient's skin. Four finished electrodes are placed into a protective pouch. The pouches are sealed and boxed for shipping.

**5. Intended Use:**

The proposed Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode is intended for over-the-counter use with transcutaneous electrical stimulation devices to provide the conductive interface between the stimulation device and the patient's skin. The starburst gradient pattern is designed to provide optimal current distribution during electrotherapy.

**6. Technological Characteristics:**

The OTC Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode exhibits identical technological characteristics as compared to the predicate prescription Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode (K083350). The electrode is composed of a cover, reinforcement film, lead wire, glue, silver print, conductive member, conductive hydrogel, pressure sensitive adhesive, and a release liner.

**7. Performance Data:**

No performance data was required to support this premarket notification as the proposed OTC Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode has identical technological characteristics, including design and materials, as compared to the currently marketed predicate prescription Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode (K083350). This premarket notification supports a change to the product labeling only to allow the product to be sold for over-the-counter (OTC) use.

**8. Conclusion:**

Based on an evaluation of the labeling for the proposed and predicate devices, Covidien believes that the proposed OTC Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode is suitable for over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Covidien
Medical Supplies
c/o Mr. Wing Ng
15 Hampshire St
Mansfield, MA 02048

SEP 3 2010

Re: K100418
Trade/Device Name: Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 27, 2010
Received: August 30, 2010

Dear Mr. Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

SEP 3 2010

**510(k) Number (if known):** **K100418**

**Device Name:** Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode

**Indications For Use:**

The Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode is indicated for use with transcutaneous electrical stimulation devices to provide the conductive interface between the stimulation device and the patient's skin.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100418